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In The Supreme Court of the United States

RICHARD E. GLOSSIP et al.,

Petitioners,

v.

KEVIN J. GROSS et al.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit

BRIEF FOR RESPONDENTS

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QUESTIONS PRESENTED

1. Does a three-drug lethal injection protocol create a substantial risk of severe pain in violation of the Eighth Amendment when the first drug is highly likely to render the offender unconscious and insensate during the remainder of the execution procedure?

2. Does the *Baze*-plurality stay standard apply when states are not using a protocol substantially similar to the one that this Court considered in *Baze*?

3. When bringing an Eighth Amendment challenge to method of execution under 42 U.S.C. § 1983 must a claimant establish the availability of an alternative method of execution?

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

Relevant constitutional and statutory provisions are reprinted at App. 1a, *infra*.

INTRODUCTION

In the dosage called for by Oklahoma's execution protocol, midazolam "is highly likely to render [Petitioners] unconscious and insensate" during their executions. So found the district court, in thorough factual determinations that were affirmed by the court of appeals on clear error review.

Petitioners' allegation-laden opening brief asks the Court to assume the role of a court of error and to substitute Petitioners' proffered facts for the district court's factual findings. But the facts determined by both courts below are well-supported by the record and medical literature, and they make plain that Oklahoma's lethal injection protocol is not cruel and unusual, but rather the most humane form of execution available to the State.

Fact-bound calls to "intrude on the role of [States] in implementing their execution procedures," *Baze* v. *Rees*, 553 U.S. 35, 51 (2008), properly give this Court pause. As a sovereign State vested with the extraordinary responsibility of carrying out the sentences of death meted out by its citizens as punishment for the most heinous crimes, Oklahoma attempts to execute those sentences as humanely, painlessly, and in as

dignified a manner as possible within the means available to it. And "by all accounts," Oklahoma has "fulfilled [its role] with an earnest desire to provide for a progressively more humane manner of death." *Ibid.*

It was Oklahoma that in 1977 tasked its medical experts with developing a more humane alternative to electrocution. The resulting three-drug lethal injection protocol was adopted by every jurisdiction in the United States. When death penalty opponents' attacks on the effectiveness of the first drug, sodium thiopental, proved unsuccessful, they turned to cutting off supplies to the States. Oklahoma led the switch to pentobarbital, which too was adopted by virtually every jurisdiction. Pentobarbital acquired a well-established record of reliability and effectiveness, despite the same accusations that it could not reliably lead to painless executions.

And now, after death penalty opponents have pressured manufacturers of pentobarbital to cut off supplies to the States, Oklahoma again has found itself thrust to the forefront of the search for an acceptable – and available – alternative that will allow it to carry out the sovereign duty assigned to it by the people of Oklahoma. As the district court found, Oklahoma has reasonably determined that alternative to be a drug called midazolam.

As those before them did with sodium thiopental and pentobarbital, Petitioners argue that it is unconstitutionally cruel and unusual for Oklahoma to use a massive dose of midazolam in order to render them

unconscious prior to administration of the drugs that will cause their deaths. Specifically, they argue that the risk that they might be able to perceive pain despite the midazolam – a risk patients and doctors accept every day in undertaking otherwise-painful procedures after administration of a much smaller dose of midazolam – is so substantial as to render the use of midazolam the constitutional equivalent of drawing, disemboweling, and quartering. This cannot be so.

Worse still, feigning ignorance of the very drug shortage that their supporters helped create, Petitioners allege that Oklahoma turned to midazolam not in a good faith effort to find the best available alternative drug but out of callous "expediency." All the while, Petitioners steadfastly refuse to identify a single better option available to Oklahoma. This fact alone demonstrates that this case, under the guise of a narrow attack on a single method of execution out of many, is a full-throated attack on the ability of the sovereign States to carry out the death sentences issued by their citizens.

For these and other reasons, the case should be resolved by either (1) dismissal of the petition for certiorari due to its fact-bound nature and failure to present any question of law upon which there is a lack of uniformity in the lower courts, or (2) affirmance of the Tenth Circuit's judgment.

STATEMENT OF THE CASE

I. Factual Background

A. Midazolam

Midazolam was "developed as a water-soluble benzodiazepine anesthetic agent." Sze-Chuh Cheng & Edward Brunner, *Inhibition of GABA Metabolism in Rat Brain Synaptosomes by Midazolam*, 55 Anesthesiology 41, 41 (1981). It is a "potent sedative agent" with a long record of effective use as a sedative, induction agent, and anesthetic for painful procedures such as intubation, gastroscopy, and cardiac catheterization. FDA-Approved Label for Midazolam, Expert Report of Larry Sasich, Ex. 2, 1.usa.gov/1GLozGY ("Midazolam's FDA Label"); Tr. of Prelim. Inj. Hr'g 368, 599 (Doc. 178) ("Tr."); J.A.76; J.A. vol. II 53 ("J.A.II"). Although most benzodiazepines cannot produce "surgical anesthesia * * * in the absence of other drugs" that depress the central nervous system ("CNS"), "an important exception is midazolam." Dennis S. Charney et al., *The Pharmacological Basis of Therapeutics* 401 (11th ed. 2006); George Brenner & Craig Stevens, *Pharmacology* 192 (4th ed. 2013) ("higher doses [of benzodiazepines] produce * * * anesthesia," even though other "*orally administered* benzodiazepines do not produce significant respiratory depression, coma, or death") (emphasis added).

According to Midazolam's FDA Label, the drug's "efficacy and safety * * * are functions of the dose administered, the clinical status of the individual patient, and the use of concomitant medications capable

of depressing the CNS," and "[a]nticipated effects range from mild sedation to deep levels of sedation virtually equivalent to a state of general anesthesia where the patient may require external support of vital functions." See *supra*. The FDA warns that when a higher-than-therapeutic dose is given, "coma" can result, and that other "serious cardiorespiratory adverse events have occurred * * * [including] respiratory arrest and/or cardiac arrest, sometimes resulting in death." *Ibid.*; J.A.250.

Midazolam's effectiveness as an induction agent has been well-known since at least 1985, when what Petitioners' expert anesthesiologist described as the "landmark" study on midazolam, J.A.230, concluded that "midazolam may be used intravenously for the induction of anesthesia" at doses from 0.1 to 0.4mg/kg. J. G. Reves et al., *Midazolam: Pharmacology and Uses*, 62 Anesthesiology 310, 317-18 (1985). The study describes midazolam as an alternative to sodium thiopental for induction of anesthesia and other purposes. *Id.* at 312, 317, 324. Indeed, "double-blind studies comparing midazolam and thiopental induction and maintenance [of anesthesia]" found that midazolam "proved superior to thiopental because there were fewer adjuvant anesthetics required to maintain an adequate depth of anesthesia" and because it "confers more amnesia." *Id.* at 318.[1]

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[1] Another study Petitioners' expert anesthesiologist relied on, J.A.233-34, concluded that, in dogs, an infusion rate of 450

(Continued on following page)

Today, thousands of surgeries are performed daily on patients who have been administered a small, 2 to 5mg therapeutic dose of midazolam. This dosage serves two primary purposes. First, it relieves the patient's anxiety and serves as a powerful sedative. Second, the drug has a strong effect on the patient's ability to register and remember pain. See Petra Bischoff & Ingrid Rundshagen, *Awareness Under General Anesthesia*, 108 Deutches Ärzteblatt Int'l 1 (2011), 1.usa.gov/1LSpQjX. Midazolam is also sometimes administered at a higher dose in order to effect not just sedation, but also unconsciousness during intubation and other painful procedures that must be done in preparation for surgery. Once unconscious and intubated, inhaled anesthetics are typically administered to maintain general anesthesia for the remainder of the surgery.

Small doses of midazolam are also routinely used as the sole anesthetic for painful, invasive procedures

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μg/kg/min (31.5mg/min for a 70kg person) of midazolam could be utilized as a sole-anesthetic. Richard I. Hall et al., *The Anesthetic Efficacy of Midazolam in the Enflurane Anesthetized Dog*, 68 Anesthesiology 862, 865 (1988). Notably, 2.5 times more midazolam is required to create the same anesthetic effects in dogs as is required for humans. Yoshimi Inagaki et al., *Anesthetic Interaction Between Midazolam and Halothane in Humans*, 76 Anesthesia & Analgesia 613, 615 (1993). Studies on humans have found that the anesthetic effects of midazolam increased linearly with dosage and estimate that 2mg/kg (140mg in a 70kg person) is enough for full surgical anesthesia. Michael Melvin et al., *Induction of Anesthesia with Midazolam Decreases Halothane MAC in Humans*, 57 Anesthesiology 238 (1982).

like endotracheal intubation, colonoscopies, and gastroscopies.[2] For example, midazolam is used as the sole anesthetic for "rapid sequence intubation," which involves "the administration * * * of a potent induction agent followed immediately by a rapidly acting neuromuscular blocking agent," such as rocuronium bromide, "to induce unconsciousness and paralysis for tracheal intubation."[3] The use of a small 0.1-0.2mg/kg dose to render the patient unconscious and unaware of pain is important in rapid sequence intubation because "[w]hen a paralytic agent is used for intubation without sedation, the patient may be fully aware of his or her environment, including pain, but unable to respond." Caro, n.3, *supra*.

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[2] One study found that many patients who had undergone intubation without anesthesia rated the procedure as a "10 out of 10" on the pain scale. Armando J. Rotondi, *Patients' recollections of stressful experiences while receiving prolonged mechanical ventilation in an intensive care unit*, 30 Critical Care Med. 746, 748 (2002); see also *Howell* v. *State*, No. SC14-167, IX Supp.R. 253-54 (Fla. Feb. 13, 2014) (Dr. Mark Dershwitz testifying that midazolam is able to maintain unconsciousness during intubation, "which all anesthesiologists consider to be an extraordinarily noxious degree of stimulation").

[3] Ron Walls & Michael Murphy, Manual of Emergency Airway Management 221-24 (2012); see also Tr.591; J.A.II.53; David Caro, *Sedation or induction agents for rapid sequence intubation in adults*, UpToDate (Feb. 24, 2015), bit.ly/1BIFX9G; T. Nishiyama et al., *Midazolam for rapid sequence induction*, 39 Japanese J. of Anesthesiology 230 (1990).

Midazolam is also used as the sole anesthetic for dental extractions, J.A.307, and correction of arrhythmias using painful electrical shocks, A.R.J. Mitchell et al., *Diazepam or midazolam for external DC cardioversion*, 5 Eurospace 391 (2003); A. Gupta et al., *Anaesthesia for cardioversion*, 45 Anaesthesia 872 (1990). "[I]n very high doses" midazolam "will completely ablate" or "completely destroy" consciousness. *Muhammad* v. *Sec. Fla. Dept. of Corrections*, No. 3:13-cv-1857, Doc. 1-3, 20 (M.D. Fla. Dec. 23, 2013) (testimony of Plaintiff's expert anesthesiologist Dr. Heath). Thus, although it is not "common to use midazolam for general anesthesia" because other drugs are better suited for "the usual goal [of having] the patient wake up rapidly at the end of the operation," during drug shortages midazolam has been used "as the first and primary drug to induce general anesthesia for surgeries," including brain surgery, in a 50mg dose with no other anesthetic or analgesic. *Howell*, *supra* n.2, IX Supp.R. at 217-19, 233-34; Tr.621-23. Finally, during end-of-life palliative care, where medication is used "to relieve intolerable suffering * * * by a reduction in patient consciousness" and awareness, sometimes to "continuous and deep" levels, midazolam is recommended as the "first-line choice." Alexander de Graeff & Mervyn Dean, *Palliative Sedation Therapy in the Last Weeks of Life*, 10 J. Palliative Medicine 67 (2007).

B. Oklahoma's Lethal Injection Protocols

Oklahoma developed lethal injection as a method of execution in 1977, after the Oklahoma Legislature directed the state medical examiner to find a more effective and humane alternative to electrocution. That protocol included (1) sodium thiopental, a fast-acting barbiturate that caused unconsciousness, (2) vecuronium bromide, a neuromuscular blocking agent that inhibited all muscular-skeletal movements and, by paralyzing the diaphragm, stopped respiration,[4] and finally (3) potassium chloride, which interfered with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest. *Baze* v. *Rees*, 553 U.S. 35, 44 (2008).

This protocol proved highly effective. By 2008, when this Court decided *Baze*, virtually every jurisdiction with the death penalty had adopted the protocol. *Baze*, 553 U.S. at 42-43.

Once *Baze* effectively foreclosed further challenges to the protocol, anti-death penalty activists began

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[4] Unlike the circumstances in *Baze*, Oklahoma law and current veterinary guidelines for the euthanasia of animals allow the use of neuromuscular blocking agents so long as the animal is "anesthesized or unconscious" prior to administration of the paralytic. American Veterinary Medical Association, Guidelines for the Euthanasia of Animals 34 (2013), bit.ly/RVjJAW.

pressuring manufacturers of sodium thiopental to restrict its sale to States so that the States would be forced to alter the protocol, opening up new opportunities for Eighth Amendment challenges to delay executions. In 2011, "after months of pressure by activists" and under threat of legal liability in Europe, the sole American provider of sodium thiopental was forced to exit the market in the United States.[5] Supplies of sodium thiopental began to dwindle, and the drug became impossible for the States to obtain. *Pavatt* v. *Jones*, 627 F.3d 1336, 1338 n.1 (10th Cir. 2010).

In response, Oklahoma led the switch to pentobarbital, and most other States soon followed suit.[6] Pentobarbital proved highly effective, but its manufacturer began taking steps to prevent States from obtaining the drug for use in executions.[7] Supplies dwindled, and the States were again forced to begin searching for an alternative to ensure the most humane execution.

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[5] Nathan Koppel, *Drug Halt Hinders Executions in the U.S.*, The Wall Street Journal (Jan. 22, 2011), on.wsj.com/1C7ehOd.

[6] *E.g.*, *Pavatt*, 627 F.3d at 1337-38; Jim Salter, *Missouri Prisons Receive New Execution Drug, Pentobarbital*, Huffington Post (Oct. 23, 2013), huff.to/1D2uZ4I.

[7] David Jolly, *Danish Company Blocks Sale of Drug for U.S. Executions*, N.Y. Times (July 1, 2011), nyti.ms/1HOSzj2.

Some States, including Oklahoma, began sourcing pentobarbital from compounding pharmacies. Condemned inmates sued the States claiming that the use of compounded pentobarbital constituted cruel and unusual punishment. Oklahoma's supplier of compounded pentobarbital came under intense pressure from death penalty opponents to cease compounding pentobarbital for use in executions, and subsequently declined to continue supplying the drug to Oklahoma. Ltr. Pharmacy to ODOC (Doc. 64-6). After an exhaustive search for a new supplier proved fruitless, Oklahoma was forced to identify a replacement for pentobarbital. Tr.309-10, 317.[8]

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[8] Petitioners, for the first time in this litigation, suggest that pentobarbital is available to Oklahoma, Pet. Br. 47 n.29, asking Oklahoma to "explain[ ]" the unavailability – which Oklahoma has satisfactorily done to the district court and court of appeals, J.A.67, 115 – ignoring *their* burden to show that the drug *is* available. Regardless, those States that have continued to use pentobarbital rely on dwindling stockpiled supplies. Michael Graczyk, *Texas seeks to replenish low supply of execution drugs amid pending court order to ID supplier*, U.S. News & World Report (Mar. 9, 2015), bit.ly/1Gcuapt (noting supply problems with pentobarbital in Texas, South Carolina, and Georgia); Emma Lacey-Bordeaux, *Texas nearly out of execution drug*, CNN (Mar. 10, 2015), cnn.it/1N4flqL. Oklahoma has never stopped pursuing new supplies of sodium thiopental and pentobarbital, but those efforts have proven unsuccessful.

After exploring a variety of options, several States concluded that midazolam would make an effective alternative to pentobarbital.[9]

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[9] Ohio and Arizona began using midazolam as part of a conceptually different two-drug protocol, using hydromorphone (an opiate) in conjunction with midazolam to depress the inmate's respiratory drive and cause death. The protocol has been ineffective at causing a swift death, resulting in several executions taking longer than expected. Both Ohio and Arizona have announced that they will discontinue use of that two-drug protocol. Michael Kiefer, *Arizona to Change Drugs Used for Executions*, USA Today (Dec. 23, 2014), usat.ly/1yqrFJw; Matt Pearce, *Ohio Won't Use Controversial Drug Combo for Executions Anymore*, L.A. Times (Jan. 8, 2015), lat.ms/1bHp2xX. Oklahoma likewise will not use that two-drug combination. J.A.118 & n.3.

Those executions are not probative of whether the entirely different drug protocol at issue here is effective because they administered midazolam in a different dose and method than in Oklahoma and Florida's protocol. In Ohio, only 10mg of midazolam is used, which is at the bottom end of the therapeutic range used for induction. J.A.217. In the Joseph Wood execution, Arizona used fifteen 50mg doses of midazolam spread out over a nearly two hour period. M. Alex Johnson, *Arizona Needed 15 Drug Doses To Execute Joseph Wood*, NBC News (Aug. 1, 2014), nbcnews.to/1rXAQ4M. Petitioners' expert testified here that intravenous midazolam has a peak effect 2-3 minutes after injection, Tr.116, and the drug has a "brief half-life," Reves, p.5, *supra*, at 318-19. There is a significant pharmacological difference between a single, rapidly introduced 500mg dose and 50mg doses spaced out over two hours. Tr.667. Moreover, thorough reviews of those executions concluded that the inmates were "fully sedated, w[ere] totally unresponsive to stimuli, and as a result did not suffer." Mayra Cuevas, *Two-Hour Execution Followed Correct Protocol, Says Independent Report*, CNN (Dec. 22, 2014), cnn.it/1EE9LFb; see also Eyder Peralta, *Ohio Will*

(Continued on following page)

In October 2013, Florida began using midazolam as the first drug in a three-drug protocol after extensive litigation unsuccessfully challenging the constitutionality of that protocol. J.A.101-02. Florida has since conducted eleven executions using that protocol without incident.

As the Oklahoma Department of Corrections ("ODOC") began its search for a new drug, it consulted with its counterparts in other states, including Texas, Illinois, and Arizona. J.A.II.1-2, 8. Based on these consultations, ODOC's general counsel began researching midazolam by reviewing the expert testimony that was provided in federal court litigation in Florida, where Florida's use of midazolam had been unsuccessfully challenged. J.A.II.2, 4. The general counsel also consulted with ODOC's medical director, conducted research of his own,[10] and consulted with the Oklahoma Office of the Attorney General, which advised ODOC that in light of the evidence and Florida's record of successful use of midazolam, its use comports with the Eighth Amendment. J.A.II.3, 5-8; J.A.145-47. ODOC determined that, unlike the alternatives, midazolam was readily obtainable.

Increase Dosage of Drugs in Lethal Injection, NPR (Apr. 28, 2014), n.pr/1CnbXm4.

[10] Petitioners have persisted in their misleading assertion that ODOC's general counsel's research was limited to "wikileaks [sic]" when in fact the general counsel's testimony was that he "went past" such sources to perform more in-depth research into the drug. J.A.II.7.

Based on this vetting, ODOC elected to revise its protocol to include the three-drug protocol at issue here: midazolam, followed by vecuronium or recuronium bromide, then potassium chloride. J.A.145-50; Tr.297.

C. The Execution of Clayton Lockett

Oklahoma began use of the midazolam-based three-drug protocol in 2014 with the execution of Clayton Lockett. Problems with the execution began even before it started. While in his cell, Lockett cut himself in the crook of his arms in an apparent attempt to impede IV access. J.A.50. Once Lockett was transferred to the execution chamber, Oklahoma's personnel had unprecedented difficulty setting an IV. J.A.51-53. The attending physician eventually was able to set a functioning IV in Lockett's femoral artery near the groin. J.A.52. Due to the sensitive location of the IV insertion point, the ill-fated decision was made to cover it with a sheet so as to preserve Lockett's dignity. J.A.52.

Shortly after administration of the midazolam began, the IV failed; because the IV insertion point was covered, this failure was not immediately detected. J.A.53-56. Enough midazolam made it into Lockett's bloodstream to cause temporary induction of unconsciousness, but not enough to maintain an adequate level of unconsciousness. J.A.53-57. Because the IV failed, the remaining midazolam, vecuronium bromide, and potassium chloride were injected into Lockett's muscle tissue, where they were partially

and slowly absorbed, eventually causing his death. J.A.54-56.[11] It is not clear whether Lockett suffered severe pain before his death. J.A.55, 70; J.A.II.50; Tr.617.

Oklahoma immediately launched a thorough investigation to determine the mistakes made and how to prevent them. J.A.379. After a five month investigation, Oklahoma Department of Public Safety investigators concluded that Lockett's prolonged execution was caused by (1) the use of a short needle in setting a femoral IV, which rendered the IV prone to failure, and (2) the decision to cover the IV insertion point with a sheet, resulting in failure to discover the IV problems. J.A.376-419.

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[11] The concentration of midazolam found in Lockett's bloodstream was slightly higher than would be expected had Lockett received a therapeutic dose of midazolam and approximately *half* the amount than what is given to patients as anesthesia for surgery. J.A.374-75. Contrary to Petitioners' claim, Pet. Br. 20, much less than the intended 100mg dose of midazolam actually made it into Lockett's system because the IV failed *during* administration of midazolam, not after. J.A.56. Also inaccurate is Petitioners' related claim that the IV failure was irrelevant because midazolam "has a rapid absorption rate, even if not administered intravenously." Pet. Br. 20 n.22. Petitioners' own expert testified that when injected intravenously, midazolam has a peak effect at 2-3 minutes, whereas with intramuscular injection, initial effects are not seen until 10-15 minutes after injection, with peak effect occurring at approximately 60 minutes. Tr.116-17; J.A.328. Lockett began to move 10 minutes after the midazolam injection, and died 33 minutes later. J.A.392-95. Lockett's execution provides no probative evidence as to the efficacy of a correctly-administered 500mg (or 100mg) intravenous dose of midazolam.

In response, the ODOC extensively revamped its execution protocol, which included rigorous new training requirements, a complete remodel of the execution chamber and its equipment, and new monitoring requirements. J.A.57-66, 361-69.

Oklahoma's revamped execution protocol requires the presence of two medical professionals to establish and monitor IVs, determine and monitor consciousness, and pronounce death, as part of the "IV Team." J.A.58. For Petitioners' executions, the IV Team will include a physician and paramedic. J.A.63-64.

The execution room is now equipped with an ultrasound machine to locate veins when setting IVs and with all equipment medically necessary to gain IV access. J.A.66. To aid in monitoring the IVs after they are established, the execution chamber is equipped with three high-definition video cameras, one fixed over the top of the inmate and two that are capable of tilting, panning, and zooming. J.A.64. The feeds from these cameras are viewed by the IV Team on high-definition monitors in the execution room, where they can also see directly into the execution chamber through one-way glass. J.A.64. The execution room is equipped with primary and backup electrocardiograph machines to monitor the inmate's pulse, blood pressure, and respiration from the beginning of administration of the drugs until death is pronounced. J.A.66.

Once the IV Team has confirmed that the IVs are functioning, the midazolam is administered and the physician "physically confirm[s] the offender is unconscious by using all necessary and medically appropriate methods." J.A.65. Only after the physician is satisfied that the inmate is unconscious and insensate are the second and third drugs administered. During administration of those drugs, the IV Team continuously monitors the inmate, including the use of the EKG, for any indications of consciousness, and continues to do so until death is pronounced. J.A.63-65.

II. Proceedings Below

This appeal arises out of a motion for preliminary injunctions filed by four inmates on Oklahoma's death row, each scheduled to die in 2015. Charles Warner anally raped and murdered an eleven-month old girl; Richard Glossip hired his coworker to kill their employer by beating him to death with a baseball bat; John Grant murdered a food service supervisor in the correctional facility in which he was a prisoner by repeatedly stabbing her to death with a shank; and Benjamin Cole murdered his nine-month-old daughter by snapping her spine in half. J.A.49-50, 113-14.

A. Petitioners' Suit

Petitioners, along with eighteen other Oklahoma inmates sentenced to death, alleged eight counts in

their Section 1983 suit against various ODOC officials. Only Count 2 remains at issue.

Count 2 alleges that Oklahoma's use of midazolam as the first drug in the three-drug protocol creates a substantial risk that an inmate would experience "severe pain, needless suffering, and a lingering death," and thus violates the Eighth Amendment. J.A.119.

On November 10, 2014, Petitioners filed a motion for preliminary injunction asking the district court to bar Oklahoma from implementing the midazolam-based protocol and executing the Petitioners until a ruling on the merits. J.A.120. In December 2014, the district court held a three-day evidentiary hearing on the motion for preliminary injunction. *Ibid.*

B. Petitioners' Expert Witnesses

Petitioners presented two expert witnesses on the subject of midazolam's properties: anesthesiologist David Lubarsky and pharmacist Larry Sasich.

1. Dr. David Lubarsky. Lubarsky is a frequent witness for challengers to the constitutionality of lethal injection and has long been a crusader against the use of sodium thiopental in lethal injections. His "zeal" to end the use of three-drug protocols has prompted criticism by even those who otherwise agree with his opposition to lethal injection. See, e.g.,

Groner, *Inadequate Anaesthesia in Lethal Injection for Execution*, 366 Lancet 1073, 1073 (2005).[12]

Lubarsky's claims about the inappropriateness of sodium thiopental sparked the litigation that culminated in this Court's decision in *Baze*, 553 U.S. at 67 (Alito, J., concurring), but the Court ultimately was not persuaded by the claims Lubarsky made in his article *Inadequate Anaesthesia in Lethal Injection for Execution*, 365 Lancet 1412 (2005). The *Baze* plurality noted the "controversy surrounding" Lubarsky's scholarship, pointing to the "peer responses by seven medical researchers criticiz[ing] the methodology supporting the [article's] original conclusions," *Baze*, 553 U.S. at 51 n.2. Justice Alito likewise pointed out that Lubarsky's article had been "questioned," *id.* at 67, while Justice Breyer described Lubarsky's scholarship as perhaps "seriously flawed" and incapable of being given "significant weight," *id.* at 109 (citing Groner, *supra*). See also *West* v. *Schofield*, 380 S.W.3d 105, 114-16 (Tenn. 2012) (rejecting Lubarsky's opinions on sodium thiopental).

Once the States began replacing sodium thiopental with pentobarbital, Lubarsky shifted his criticisms to that drug. When called as an expert witness in a

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[12] Lubarsky's criticisms of sodium thiopental were similar to those he now levies at midazolam. For example, he claimed that thiopental was improper because it "is used solely to induce a few moments of anesthesia prior to administering additional agents." David A. Lubarsky et al., *Lethal Injection for Execution: Chemical Asphyxiation?*, 4 PLoS Med. 646, 650 (2007), bit.ly/19MwZ4q.

challenge to Alabama's use of pentobarbital, Lubarsky raised now-familiar attacks, claiming it was "designed to produce sedation, not anesthesia" and that the FDA had not approved it for use as "an anesthesia induction agent." *Arthur* v. *Thomas*, 674 F.3d 1257, 1266 (11th Cir. 2012) (Hull, J., dissenting). Lubarsky argued that "there is no scientific literature establishing the anesthetic dose of pentobarbital" and that the dose of pentobarbital to be given could not reliably "assure that an inmate is unconscious when given pancuronium bromide and potassium chloride." *Ibid.*

As was the case with his opinions regarding sodium thiopental, Lubarsky's opinions regarding pentobarbital never won the day. Both drugs proved effective at rendering inmates unconscious and insensate.

Undeterred, Lubarsky claimed to the district court here that "all" of Oklahoma's drug protocols, including those using sodium thiopental and pentobarbital, were "actually constructed to produce egregious harm and suffering," and that even properly administered, sodium thiopental was "insufficient to render a patient unconscious through the entirety of the execution," J.A.226-27 – a claim even the challengers in *Baze* distanced themselves from.

Lubarsky's campaign has now shifted to midazolam. Lubarsky testified to the district court in this suit that he had overseen the administration of midazolam "a million times," both for sedation and to induce anesthesia. J.A.203-04. In his experience, a 2

to 5mg dose was typical for sedation, while a 30 to 50mg dose was typical for inducing anesthesia. J.A.217. Lubarsky agreed that deaths had occurred from midazolam at doses as small as .04 to .07mg/kg (for a 70kg patient, 2.8 to 4.9mg). J.A.217. He argued, however – without citing any source – that "those type of fatalities occur in 90-year-olds with congestive heart failure who have not had careful titration of the drug," *ibid.*, a claim undermined by Midazolam's FDA Label, which warns of "serious and life-threatening cardiorespiratory adverse events" requiring monitoring "regardless of age or health status."[13]

Lubarsky conceded that if someone were administered a 500mg dose of midazolam intravenously, it would take "[n]o more than a couple of minutes for sure, probably less" for them to be rendered unconscious. Tr.117. Lubarsky likewise did not dispute that such a dose was capable of placing someone in a "surgical plane of anesthesia"; rather, Lubarsky's criticism of midazolam was that, in his estimation, it could not "reliably" place someone in that deep level of unconsciousness. J.A.228. When pressed as to how

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[13] These deaths are well-documented in the literature. See, e.g., Peter L. Bailey et al., *Frequent Hypoxemia and Apnea after Sedation with Midazolam and Fentanyl*, 73 Anesthesiology 826, 826 (1990) (noting "[m]ore than 80 deaths have been associated with the use of midazolam" in "surgical procedures in the United States"); *Reducing Risk of Midazolam Overdose in Adults*, National Patient Safety Organization (Dec. 9, 2008), http://bit.ly/18UybBK (describing deaths of patients after low doses of midazolam); J.A.309.

he reached this conclusion, Lubarsky admitted that he could not opine as to a specific degree of reliability because "no one is ever given doses like this." Tr.145.

Lubarsky speculated that the alleged lack of reliability was due to midazolam's alleged "ceiling effect." J.A.171-72. In support of this claim, Lubarsky's report cited two sources. One concerned the EEG effect of midazolam in rats, Suzanne Hovinga et al., *Pharmacokinetic-EEG effect relationship of midazolam in aging BN/BiRij rats*, 107 Brit. J. Pharmacol. 171 (1992), and the other was a material safety data sheet on midazolam, J.A.179-83. Neither source makes any mention of a "ceiling effect" or the level of consciousness at which that effect would occur.[14] Lubarsky was

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[14] In a declaration submitted on appeal and never presented to the district court, Lubarsky referenced two other sources for his claim that there was a "clearly demonstrated" ceiling effect. J.A.233-34. First, in a study on 15 dogs (only 5 of which were given high doses) seeking to determine if the amount of inhaled anesthetic necessary for surgery could be reduced by combining it with midazolam, the authors theorized that midazolam "may" have a ceiling effect but also noted that the data only showed that the effects from midazolam *slowed* at a certain level, but not ceased. Hall, *supra* n.1.

Lubarsky claims that his second after-the-fact source noted a ceiling effect at approximately 0.3mg/kg. J.A.233 (citing D. J. Greenblatt et al., *Kinetics and EEG effects of midazolam during and after one-minute, one-hour, and three-hour intravenous infusions*, 44 J. Clin. Pharmacol. 605 (2004). The study – which, contrary to Lubarsky's claims, was not aimed at determining any ceiling effect – examined "8 volunteers [who] received midazolam (0.1 mg/kg) by constant-rate intravenous infusion." *Id.* at 605. There is no mention of any 0.3mg/kg dose as claimed by Lubarsky, much less any "ceiling effect." *Id.* at 606.

unable to render an opinion as to the dosage at which this alleged ceiling effect occurred. J.A.225.

Lubarsky also argued that the risk of paradoxical reactions and the lack of analgesic effect rendered midazolam ineffective as an anesthetic. As to the former, Lubarsky claimed that in "1 to 11 percent" of cases, rather than sedating a patient and reducing their anxiety, benzodiazepines have the opposite effect, and cause agitation and an "outward manifestation that looks like anxiety." J.A.210-11. In his expert report, Lubarsky agreed that paradoxical reactions "are not attended by the expected sedative effects," J.A.172-73, but on the stand, Lubarsky for the first time claimed that paradoxical reactions can occur *after* sedation, based on unspecified "case reports." J.A.228.

On analgesia, Lubarsky argued that because midazolam is not an analgesic, it is unsuitable for use as a sole anesthetic. J.A.171. He claimed in this regard that "midazolam differs significantly and materially from barbiturates like pentobarbital, which are approved as sole anesthetics." J.A.172. However, the FDA-approved drug label for pentobarbital does not list induction or maintenance of anesthesia as an approved indication or usage, and states that pentobarbital has "little analgesic action" and "may increase the reaction to painful stimuli." DailyMed, *Label: pentobarbital sodium injection* (May 2012), 1.usa.gov/1COEl25; *Arthur*, 674 F.3d at 1266; J.A.261-62.

Lubarsky also claimed that midazolam was "deemed insufficient for surgical anesthesia in any dose form by the FDA," Tr.145, a claim contradicted by his co-expert, Dr. Larry Sasich, who admitted that it was unknown whether midazolam was even submitted to the FDA for consideration as a surgical anesthetic or whether instead the manufacturer simply "never attempted to market the drug as an anesthetic." J.A.262, 265. Nor did Lubarsky explain the medical relevance of FDA approval, given the rampant off-label use of other drugs for general anesthesia.[18]

Lubarsky acknowledged that midazolam is frequently used "to basically get the patient off to sleep so that you can then * * * do some minor procedures" but claimed that those minor procedures were only "things that don't have a great deal of noxious stimuli, painful stimuli, like colonoscopies." J.A.223. Lubarsky later stated, however, that "midazolam unconsciousness is actually sufficient" to resist the

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[18] For example, virtually every drug used for general anesthesia in pediatric patients has not been approved by the FDA for that purpose, yet that use is widely accepted in the medical community. D. R. Doherty, *Off-label drug use in pediatric anesthesia and intensive care according to official and pediatric reference formularies*, 57 Can. J. Anaesthesiology 1078, 1078-79 (2010); see also James Aisenberg, *Propofol Use Under the Direction of Trained Gastroenterologists: An Analysis of the Medicolegal Implications*, 101 Am. J. Gastroenterology 707 (2007); Nancy Chang et al., *What's in a Label?*, 103 Anesthesiology 179, 181-83 (2005) (describing many off-label uses in anesthesiology).

painful noxious stimuli associated with the setting of a femoral IV, a process that involves "digging dee[p] into the tissue," to access the femoral vein, which "is buried deep, usually a couple of inches below the skin's surface." J.A.229.

2. Dr. Larry Sasich. Sasich was educated as a pharmacist, but describes himself as a "drug information" specialist. J.A.257. Sasich currently operates a company that publishes "Patient Drug News Limited." Like Lubarsky, Sasich opined that midazolam was "inappropriate" as a lethal injection drug for three reasons: (1) lack of analgesia, (2) alleged ceiling effect, and (3) risk of paradoxical effects. J.A.260.

Regarding analgesia, Sasich simply noted that midazolam had not been approved by the FDA for use as an analgesic, without any explanation as to why this was relevant to its effectiveness as an anesthetic. J.A.261.

Regarding ceiling effect, Sasich based his conclusion that midazolam has a ceiling effect primarily on the fact that "*all* drugs essentially have a ceiling effect." Tr.343 (emphasis added). Sasich testified that he "did a [literature] search to try and determine at what dose of midazolam you would get a ceiling effect for unconsciousness and I couldn't – I could not find one." Tr.344; J.A.243-44.

As to paradoxical reactions, Sasich testified that "[t]he precise risk or incident of [paradoxical] reactions cannot be calculated" because "we simply don't have th[e] information" for midazolam. Tr.348;

J.A.244. In his expert report, Sasich's only support was two case reports of paradoxical reactions – both of which stated that at no point did patients feel pain during surgery or examination – out of millions of administrations of midazolam every year, demonstrating the extraordinary rarity of such paradoxical reactions. J.A.245.

C. Respondents' Expert Witness

On the subject of the efficacy of midazolam, Oklahoma called Dr. Lee Evans, a doctor of pharmacy who currently serves as Dean of Auburn University's School of Pharmacy. Dr. Evans' testimony regarding the use of midazolam in identical execution protocols has been relied upon by several courts. See, e.g., *Chavez* v. *Florida*, 742 F.3d 1267, 1270-71 (11th Cir. 2014), cert. denied, 134 S. Ct. 1156 (2014); *Howell* v. *State*, 133 So.3d 511, 519-22 (Fla. 2014), cert. denied, 134 S. Ct. 1376 (2014); *Muhammad* v. *State*, 132 So.3d 176, 188, 193-96 (Fla. 2013), cert. denied, 134 S. Ct. 894 (2014).

Dr. Evans testified that, when used as a pre-anesthetic sedative, the typical therapeutic dose for 70kg adult under the age of 60 would be 1.5 to 3.5mg. J.A.308. Like Dr. Lubarsky, Dr. Evans testified that fatalities have occurred from midazolam in doses as

low as 0.04 to 0.07mg/kg (2.8 to 4.9mg for a 70kg adult). Compare *ibid.* with J.A.217.[16]

Dr. Evans agreed that midazolam "is not an analgesic," but testified that this was irrelevant because a 500mg intravenous dose of midazolam would depress the central nervous system to a point that would "render the person unconscious and 'insensate' during the remainder of the procedure." J.A.309-11. In Dr. Evans' opinion, "the proper administration of 500mg of midazolam * * * make it a virtual certainty that any individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from application of the 2nd and 3rd drugs." *Ibid.*

Dr. Evans explained that midazolam's anesthetic effect stemmed from its depression of the central

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[16] Petitioners question Dr. Evans on the basis that a material safety data sheet for midazolam described a lowest reported toxic dose as being 71mg/kg, but Dr. Evans in his report described the lowest reported toxic dose as .071mg/kg. This discrepancy was the result of Dr. Evans having inadvertently attached the data sheet for preservative-free midazolam – a data sheet that contains an apparent typographical error. The data sheet from that manufacturer for midazolam containing preservatives – which all parties acknowledge is the midazolam used by Oklahoma, J.A.179, 251 – correctly states that the lowest reported toxic dose is 71 *micro*grams/kg, the equivalent of .071mg/kg, just as Dr. Evans stated. Bedford Laboratories Material Safety Data Sheet for Midazolam, http://www.benvenue.com/content/dam/internet/opu/benvenue/com_EN/documents/products/midazolam/MidazolamInjectionRev32007.pdf. In any event, both Dr. Evans and Dr. Lubarsky agreed that other sources established a history of fatalities at doses ranging from .04 to .07mg/kg. J.A.217, 294.

nervous system function by binding to gamma-aminobutyric acid ("GABA") receptors in the body. J.A.312-13. Dr. Evans testified that there are GABA receptors along the entire length of the central nervous system, not just in the spinal cord, and that midazolam binds to those GABA receptors such that the brain is effectively paralyzed, no longer capable of being aware of pain. J.A.314.

Dr. Evans agreed that paradoxical reactions were possible with midazolam, but testified that their incidence was very low, and occurred at low, therapeutic doses. J.A.315. At a 500mg dose, Dr. Evans testified, a paradoxical reaction was unlikely because the central nervous system would be effectively shut down. *Ibid.*

Regarding the "ceiling effect," Dr. Evans testified that the effect of 500mg of midazolam on GABA receptors in the brain would be such that the recipient would be rendered unconscious and insensate. J.A.312-13.

D. The District Court's Ruling

The district court issued an extensive oral ruling denying Petitioners' motion for preliminary injunction because Petitioners failed to establish a likelihood of success on the merits on any of their five claims. J.A.41. The court also concluded that Petitioners "failed to establish any of the [other] prerequisites to a grant of preliminary injunctive relief." J.A.41-42.

The district court found that "[t]he 500 milligram dosage of midazolam, as called for in * * * the revised protocol, is many times higher than a normal therapeutic dose of midazolam" and "will result in central nervous system depression as well as respiratory arrest and cardiac [ar]rest." J.A.76-77. The court further found that a 500mg dosage of midazolam "is highly likely to render the person unconscious and insensate during the remainder of the procedure" and that, "[c]onsequently, analgesia, from midazolam or otherwise, is not necessary." J.A.77. In sum, the court found that "[t]he proper administration of 500 milligrams of midazolam * * * would make it a virtual certainty that an individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from application of the second and third drugs." *Ibid.*

The district court expressly found "persuasive[ ]" the testimony of Dr. Evans that "whatever the ceiling effect of midazolam may be with respect to anesthesia * * * there is no ceiling effect with respect to the ability of a 500 milligram dose of midazolam to effectively paralyze the brain," J.A.78, "shutting down respiration and eliminating the individual's awareness of pain." *Ibid.* Likewise, the court found that even "with a low therapeutic dose of midazolam there would be less than a 1 percent incidence of a paradoxical reaction," but "[n]o data [was] available to show what * * * the likelihood of a paradoxical reaction would be with a 500 milligram IV dose of midazolam." J.A.78-79. Thus, the court determined that risk "speculative" at best. J.A.78. The court also "place[d]

considerable reliance" on certain "aspects of the [revised] lethal injection protocol" including the requirement that "the offender's level of consciousness must be monitored throughout the procedure." J.A.97.

The district court found Petitioners' allegation that "[i]t would be feasible to use sodium thiopental in a single-drug formulation to" carry out their executions groundless. J.A.124-25. In particular, the court found that "the defendants have affirmatively shown that sodium thiopental and pentobarbital * * * are not available to the DOC." J.A.68.

E. Petitioners' Appeals

A unanimous panel of the court of appeals affirmed the district court's preliminary injunction denial. J.A.113.

In response to Petitioners' claim that the district court abused its discretion by relying on Dr. Evans' testimony, the court of appeals noted that Petitioners did "not argue that the district court failed to make adequate *Daubert* findings regarding Dr. Evan's [sic] testimony." J.A.135. The court of appeals credited the "detail" with which the district court performed its gatekeeper role and concluded that "there is no question that the district court * * * applied the proper standards in doing so." J.A.133. The court of appeals likewise held that the district court "aptly" concluded that Dr. Evans' "extensive" experience and "considerable" qualifications made him well-suited to opine on the issue at hand. J.A.134.

After "carefully examining the record on appeal," the Tenth Circuit concluded that none of the district court's findings were clearly erroneous. J.A.136-37. The court noted Petitioners' criticisms of Dr. Evans' testimony but held that, even if taken as true, those criticisms did not undercut his testimony on the critical question of whether 500mg of midazolam would render Petitioners unconscious and insensate. J.A.137.

In an alternative holding, the court of appeals concluded that the district court had properly construed and applied the test articulated by this Court in *Baze*, which requires in its second prong that an inmate seeking a stay of execution "show that the risk is substantial when compared to the known and available alternatives." J.A.130 (quoting *Baze*, 553 U.S. at 61). Plaintiffs did not identify any available alternative. J.A.130. Nonetheless, this conclusion was unnecessary to the disposition of the case because "the plaintiffs have failed to establish that the use of midazolam in their executions * * * creates a demonstrated risk of severe pain." *Ibid.* (citing *Raby* v. *Livingston*, 600 F.3d 552, 560 (5th Cir. 2010)).

On January 13, 2015, Petitioners petitioned this Court for certiorari and filed an accompanying application for a stay of their executions. Respondents filed oppositions to both the next day. On January 15th, this Court denied the application for stay.

On January 23rd, this Court granted the petition for writ of certiorari. Three days later, Oklahoma filed

an application to stay the executions of the remaining Petitioners, which the Court subsequently granted.

F. The Execution of Charles Warner

After this Court denied his request for a stay, Oklahoma executed Charles Warner, using the three-drug protocol at issue here. The execution was completed without incident. Glenn Puit, *Oklahoma executes Charles Frederick Warner without incident*, EnidNews.com (Jan. 15, 2015), bit.ly/1LQOtgY.[17]

Warner "los[t] consciousness quickly." Erik Eckholm, *Oklahoma Executes First Inmate Since Slipshod Injection in April*, N.Y. Times (Jan. 15, 2015), nyti.ms/1DSMLan. Five minutes after the midazolam was administered, the attending physician checked Warner for consciousness, utilizing a variety of medical techniques. Satisfied that Warner was insensate to these stimuli, the physician informed the execution team that Warner was unconscious, and the second and third drugs were administered. Warner "showed no

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[17] Petitioners falsely imply that there were indications that the midazolam did not work in the Warner execution. Pet. Br. 22. Warner's last words were, "my body is on fire," but it is undisputed that Warner said this immediately after the administration of midazolam began and *before* injection of the second and third drugs. Petitioners' own source states, because "[Warner] began complaining about the effects on his body before the drugs were administered," it raises questions "whether he may have exaggerated his symptoms to help his fellow death row inmates' case." Sean Murphy, *Dying Oklahoma Inmate's Last Words Stir Questions*, N.Y. Times (Jan. 16, 2015), http://nyti.ms/1y0rJ2s.

physical signs of distress," and by all accounts, "it appeared the [midazolam] worked." Puit, p.32, *supra*; see also M. Delatorre, News Channel 4 (Jan. 15, 2015), bit.ly/1xe0eqT; Sean Murphy, *Inmate Shows No Obvious Distress in Oklahoma Execution*, N.Y. Times (Jan. 16, 2015). The physician and paramedic continuously monitored Warner for signs of consciousness, both visually and by monitoring an EKG which displayed Warner's vital signs. Eighteen minutes after the execution began, Warner was pronounced dead. Puit, p.32, *supra*.

SUMMARY OF ARGUMENT

I. Petitioners present no issues appropriate for resolution by this Court and their petition should be dismissed as improvidently granted. This Court is not in the practice of reviewing cases like this where (1) the asserted error consists of erroneous factual findings of two courts below; (2) the purportedly erroneous holding was not necessary to the judgment below; and (3) the courts of appeals that have addressed the issue are in agreement. Seven lower courts have uniformly rejected the specific claims raised in this case, while many more courts have uniformly rejected related claims. Review by this Court is not warranted.

II. Alternatively, the judgment of the court of appeals below should be affirmed. The district court correctly found that a 500mg dose of midazolam was

highly likely to render Petitioners unconscious and insensate for the duration of their executions. It is *not* undisputed that there is a "medical consensus" that a 500mg dose of midazolam cannot reliably put a person in a coma-like state. The record evidence indicates that a large dose of midazolam produces a level of unconsciousness sufficiently deep to render persons insensate to even extremely painful stimuli.

Petitioners' three objections to the use of midazolam are unavailing. First, midazolam's lack of analgesic properties – shared by sodium thiopental and pentobarbital – is irrelevant because after being administered the midazolam, Petitioners will be unconscious and insensate to pain. Second, the risk of paradoxical reactions to midazolam manifesting *after* Petitioners have been rendered unconscious is so low that Petitioners can point to only two reported incidents of such reactions in the decades-long history of midazolam's use. Third, Petitioners' claims concerning midazolam's "ceiling effect" amount to little more than theoretical speculation, since the dosage ceiling of midazolam has never been established and there is no evidence that any purported ceiling takes effect before a person is rendered deeply unconscious and insensate to noxious stimuli. Moreover, Oklahoma's robust procedural safeguards will eliminate any risk that Petitioners will experience severe pain during their executions. On these facts, Oklahoma's lethal injection protocol does not present a substantial risk of severe pain and cannot be considered cruel.

The district court also did not err in admitting the opinions of Oklahoma's expert, who Petitioners conceded was well-qualified and whose relevant opinions were never subject to a *Daubert* challenge. All of Petitioners' quibbles with Oklahoma's expert's opinions lack merit and the district court's reliance on that testimony – especially in view of the highly flawed testimony of Petitioners' experts – was not an abuse of discretion. Regardless, the Tenth Circuit gave Petitioners every benefit of the doubt, assuming the validity of Petitioners' disagreements with Oklahoma's expert testimony, but correctly determined that none of those issues undermined the scientific reliability of Oklahoma's evidence as relevant to the district court's factual findings.

III. Petitioners initially asked this Court to decide whether the *Baze* standard applied only to challenges to execution protocols "substantially similar" to the protocol addressed in *Baze*. By its own terms, *Baze* resolved all challenges to protocols "substantially similar" to the one challenged, then articulated the standard that governs challenges involving drug protocols that are *not* substantially similar.

Realizing that the issue presented for certiorari easily resolves in Oklahoma's favor, Petitioners now argue a different issue – that the Tenth Circuit applied too stringent a preliminary injunction standard. But the Tenth Circuit explicitly applied the "significant probability of success on the merits" standard that Petitioners request, and this Court cannot presume that the appeals court *sub silentio* applied a

different and more stringent standard. Furthermore, the district court concluded that, even applying a more relaxed preliminary injunction standard than the one requested by Petitioners here, Petitioners had failed to meet their burden for a stay.

Moreover, contrary to Petitioners' arguments, the *Baze* standard *should* apply to all stay requests. The plurality unequivocally held that "[a] stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain * * * [that] is substantial when compared to the known and available alternatives." That statement should be taken at face value.

IV. Finally, Petitioners challenge the Tenth Circuit's alternative holding – "not outcome-determinative in this case" – that interpreted *Baze* to require those challenging a method of execution demonstrate that an alternative method is available that will substantially lower the risk of severe pain as compared to the method challenged. Petitioners here did not make any such showing.

Petitioners contend that *Baze*'s alternatives requirement applies only to cases advocating an improved method in the place of a "concededly constitutional" one – which, if true, would exclude *Baze* itself. Rather, the *Baze* plurality explicitly set out to establish a broadly applicable standard in response to a concurring Justice's concern about insufficient guidance

on method-of-execution cases. Accordingly, all courts of appeals thus far agree that *Baze* applies to all challenges to a method of execution.

This Court requires Petitioners to demonstrate the availability of a constitutional alternative method of execution for good reason. Capital punishment is constitutional, and this Court has made clear that States must have a means of carrying it out, even if some pain results as an inescapable consequence of execution. Accordingly, challenges to a method of execution must demonstrate that there exists a feasible alternative method that will result in substantially less pain. Otherwise, a petitioner's challenge would constitute a challenge to the death penalty itself – an issue foreclosed by the Constitution.

ARGUMENT

I. THE PETITION SHOULD BE DISMISSED AS IMPROVIDENTLY GRANTED.

Petitioners ask the Court to reverse the detailed factual findings of a district court, affirmed by the court of appeals, which are based on the documentary record and the testimony of a concededly-qualified expert, as well as the district court's judgment that this expert testified more credibly than Petitioners' experts. The petition does not present a case that is appropriate for review by this Court, and it should be dismissed as improvidently granted.

Petitioners' primary contention is that the district court committed clear error, Pet. Br. 32-38, when it made the factual findings that, "[i]n the dosage called for by [Oklahoma's execution] protocol, midazolam * * * is highly likely to render the person unconscious and insensate during the remainder of the [execution] procedure." J.A.77. The Tenth Circuit, "[a]fter carefully examining the record on appeal," held that none of those factual findings are clearly erroneous. J.A.135-37. These same factual findings – based on the testimony of multiple experts, including the same dueling experts here – have been made by another federal district court and affirmed by another court of appeals, as well as by two state trial courts, both affirmed by that state's supreme court. See *Chavez*, 742 F.3d at 1270-73; *Howell*, 133 So.3d at 519-22; *Muhammad*, 132 So.3d at 188, 193-95.

As demonstrated below, "all of these challenges lack merit." J.A.128. Regardless, this Court is not in the practice of reviewing cases where "the asserted error consists of erroneous factual findings." S. Ct. R. 10. Not being "a court of correction of errors in fact finding," this Court is loathe "to review concurrent findings of fact by two courts below" – much less the factual findings of *seven* courts. *Exxon Co., USA* v. *Sofec, Inc.*, 517 U.S. 830, 841 (1996) (quoting *Graver Tank & Mfg. Co.* v. *Linde Air Products Co.*, 336 U.S. 271, 275 (1949)).

Petitioners also claim that the court of appeals applied the wrong standard in evaluating whether a stay should be granted, Pet. Br. 39-46, but ignore the fact that the Tenth Circuit explicitly *did* apply the standard Petitioners request. J.A.113, 120-22 & n.5, 138; see p.58, *infra*. To the extent that Petitioners are contending "the misapplication of a properly stated rule of law," review by this Court is also unwarranted. S. Ct. R. 10.

Finally, Petitioners challenge the Tenth Circuit's application of the second prong of the *Baze* test, requiring that challengers to a method of execution identify a substantially less painful and available alternative. Pet. Br. 46-52. But, as explicitly stated by the court below, this alternative holding "is not outcome-determinative in this case." J.A.130. This Court generally dismisses questions where the judgment below was resolved on other sufficient grounds. See, e.g., *Belcher* v. *Stengel*, 429 U.S. 118 (1976); *The Monrosa* v. *Carbon Black, Inc.*, 359 U.S. 180 (1959). Moreover, those courts of appeals that have addressed this issue are in unanimous agreement with the Tenth Circuit, see pp.61-62, *infra*, providing yet another reason why review is unwarranted or premature, see S. Ct. R. 10(a).

Capital litigation, especially at the preliminary injunction stage, is often an expedited exercise. This case is no exception: Oklahoma had one day to respond to the petition for a writ of certiorari and applications

for stays of execution, and the Court granted certiorari after this highly-compressed briefing schedule in less than two weeks. "Now that plenary consideration has shed more light on this case" and the Court has had a full opportunity to consider the merits, it is apparent that the petition presents no appropriate issues for resolution by this Court and should be dismissed as improvidently granted. *Belcher*, 429 U.S. at 119-20.

II. OKLAHOMA'S USE OF MIDAZOLAM DOES NOT CREATE A "SUBSTANTIAL RISK OF SERIOUS HARM" TO PETITIONERS.

From the firing squad, to electrocution, to lethal injection, "[t]his Court has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." *Baze*, 553 U.S. at 41-42, 47-49 (citations omitted). This Court has speculated that a method of execution could violate the Eighth Amendment if it inherently involves "torture or a lingering death," is "inhuman and barbarous," or was calculated to "superadd[ ]" "terror, pain, or disgrace" to the execution, reflecting a "deliberate infliction of pain for the sake of pain." *Id.* at 48-49 (citations omitted). In "attack[ing] the judgment of the representatives of the people," however, those challenging a method of execution bear a "heavy burden" to show the State's choice is "cruelly inhumane" in order to prevail on

an Eighth Amendment claim. *Gregg* v. *Georgia*, 428 U.S. 153, 175 (1976).

In *Baze*, this Court considered whether Kentucky's three-drug protocol for execution – the successive injection of sodium thiopental, pancuronium bromide, and potassium chloride – violated the Eighth Amendment. *Baze*, 553 U.S. at 44, 49. The Court upheld the protocol and held that a method of execution could be cruel and unusual if it "creates a substantial risk of serious harm" that is "objectively intolerable" and is "sure or very likely to cause * * * needless suffering" when compared to alternatives that are "feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain." *Id.* at 50-52.

Oklahoma's similar protocol does not expose Petitioners to "a substantial risk of severe pain" that would produce "torture or a lingering death." Petitioners' misapprehension of the law and misstatement of the facts notwithstanding, the courts below correctly found that the dose of midazolam called for in Oklahoma's protocol is "highly likely to render [Petitioners] unconscious and insensate" during their executions and therefore Petitioners had not demonstrated a substantial probability that Oklahoma's protocol presents "an objectively intolerable risk of harm" in violation of the Eighth Amendment. J.A.77, 96.

A. Oklahoma's Protocol Is Highly Likely To Render Petitioners Unconscious And Insensate To Severe Pain During Their Execution.

1. Midazolam is a potent sedative used by physicians to depress the central nervous system for the induction and maintenance of anesthesia. Midazolam's FDA Label warns that large doses of midazolam can produce coma and death. See also Tr.661. Midazolam induces anesthesia at doses from 0.1 to 0.4mg/kg (7 to 28mg for a 70kg person), causing unconsciousness and eliminating the brain's registration and awareness of pain. See pp.5-9, *supra*. Studies of midazolam indicate that, at a large dose, it can fully replace other drugs as a sole anesthetic. *Supra* n.1. At a bolus dose of 500mg, the State and the Petitioners' experts agreed that "midazolam would produce unconsciousness" at a level "render[ing] a prisoner insensate" to painful and noxious stimuli, like "setting a femoral IV line," which involves "digging deep[ ] into the tissue, * * * a couple of inches below the skin." J.A.77-78, 302; Tr.668.

Accordingly, the district court correctly found that, as used in Oklahoma's protocol, midazolam "is highly likely to render the person unconscious and insensate during the remainder of the [execution] procedure" and will "make it a virtual certainty that any individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from the application of the second and third drugs." J.A.77. These factual findings are reviewed by this Court for clear error, *e.g.*, *Highmark* v. *Allcare*

Health Management System, Inc., 134 S. Ct. 1744, 1748 (2014), and on these facts, the district court and the court of appeals did not abuse their discretion in concluding that Petitioners failed to establish a likelihood of success on their Eighth Amendment claim.

2. Recognizing that there is little chance of overturning the district court's factfinding on clear-error review, Petitioners attempt to avoid the clear error standard on the ground that "the undisputed facts alone" establish an Eighth Amendment violation. Pet. Br. 28-32. Petitioners' transparent attempt to secure *de novo* review fails because Respondents (backed by the district court's factfinding) contest nearly all of the facts Petitioners allege, as well as the legal conclusions Petitioners draw from them.

Respondents maintain, and the district court found, that a 500mg dose of midazolam would reliably keep Petitioners unconscious and insensate throughout the execution. This fact alone renders Oklahoma's protocol constitutional.

Petitioners disregard this fact, arguing that *Baze* requires a "deep, coma-like unconsciousness" in order for the latter two drugs to be administered constitutionally – regardless of whether the condemned is unaware of pain or the amount of pain they experience. Pet. Br. 28-30. But the particular facts of *Baze* did not establish a constitutional floor for the three-drug protocol. While the Court concluded in *Baze* that any lethal injection protocol "substantially similar" to the one at issue there would be constitutional, the

Court did not conversely hold that only protocols that are "substantially similar" could survive Eighth Amendment scrutiny. *Baze*, 553 U.S. at 61.

The Court never held, and Oklahoma here has never conceded, that administration of the latter two drugs on someone not in a "deep, comalike unconsciousness" would in all instances violate the Constitution. A prisoner unaware or substantially unaware of the pain of the second or third drugs does not experience a constitutionally unacceptable level of pain, regardless of the exact depth of consciousness.[18]

Regardless, it is *not* undisputed, much less is there any medical consensus, that a 500mg dose of midazolam cannot reliably put a person in a comalike state. As noted above, the record evidence indicates that a large dose of midazolam causes a coma and produces unconsciousness sufficiently deep to render persons insensate to even extremely painful stimuli. The study cited by Petitioners' own expert

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[18] Even for patients not completely unconscious, midazolam "significantly reduce[s] * * * the pain experience." P. Coulthard & J.P. Rood, *An investigation of the effect of midazolam on the pain experience*, 30 Br. J. Oral & Maxillofacial Surgery 248 (1992). Thus, studies on humans seeking to determine the anesthetic effects of different dosages of midazolam involved reducing anesthesia during surgery until "movement occurred in response to surgical incision." Inagaki, *supra* n.1, at 614; Melvin, *supra* n.1, at 239. If the minimal awareness of that pain under the heavy anesthetic effects of midazolam is not too cruel for approved medical studies, it cannot violate the Eighth Amendment.

concluded that the dose used by Oklahoma would be sufficient to use as a sole surgical anesthetic. *Supra*, n.1.

B. The District Court Did Not Err By Relying On Oklahoma's Concededly-Qualified Expert Instead Of Petitioners' Expert.

1. Petitioners conceded that Oklahoma's expert was well-qualified to render expert opinions on the pharmacological effects of midazolam, and did not challenge the reliability of his opinions on this subject. J.A.34. Petitioners now belatedly argue that the district court erred by allowing Dr. Evans to offer expert opinions. Each of the criticisms levied at Dr. Evans are criticisms that could have been raised prior to the preliminary injunction hearing or could have been the subject of cross-examination by Petitioners' counsel, followed by an oral *Daubert* motion. Having not raised this challenge below, it is waived. *Macsenti* v. *Becker*, 237 F.3d 1223, 1230-34 (10th Cir. 2001), cert. denied, 533 U.S. 950 (2001); *Marbled Murrelet* v. *Babbitt*, 83 F.3d 1060, 1066-67 (9th Cir. 1996).

2. In any event, Petitioners' attacks on Dr. Evans do not undermine the reliability of his testimony. *First*, any opinion as to the effect of a 500mg dose of midazolam necessarily must be extrapolated from known information about lower doses because,

as Petitioners' expert acknowledged, "no one is ever given doses like this," since they are likely to be lethal to a patient or clinical subject. Tr.145; J.A.176. Because Midazolam is commonly used to induce unconsciousness during painful procedures, even Petitioners' expert opined that a 500mg dose would produce unconsciousness. J.A.77, 212. Extrapolations are used in the studies Petitioners' expert cites. Hall, n.1, *supra*. Further, the sparse medical literature on the subject does not establish a "ceiling effect" for midazolam but merely speculates about its potential existence. P.53, *infra*.

Second, Dr. Evans' extrapolations were not based on "an egregious mathematical error." Pet. Br. 35-36. Dr. Evans' expert report contains the correct lowest toxic dose of around 0.07mg/kg, which both parties' experts agreed upon, J.A.217, and which is about 100 times less than a 500mg dose for a 70kg person. *Supra* n.16. Deaths caused by midazolam, far from "unsubstantiated anecdotes," Pet. Br. 35, are well documented in the medical literature. *Supra* n.13. The only unsubstantiated testimony on this subject is Petitioners' expert's less-than-believable assertion that these dozens of reported deaths only occurred in patients who were nearly a century old, had heart failure, and were improperly administered the drug, Pet. Br. 35 (citing J.A.217), which is contradicted by Midazolam's FDA Label with a warning of

"life-threatening" effects applying "regardless of age or health status."[19]

Third, Petitioners' criticism of the shorthand way in which Dr. Evans orally described the actions of midazolam to a lay court are contrived, at best. "The most widely accepted hypothesis" for midazolam's mechanism of action is that midazolam (1) attaches to GABA receptors and (2) "interferes with reuptake of GABA, thereby causing accumulation of GABA," both of which result in central nervous system depression. Inagaki, *supra* n.1, at 616; see also Cheng, *supra*, at 44 ("Midazolam action can therefore be attributed to inhibition of GABA uptake."). Dr. Evans testified, in shorthand terms, that midazolam works in two ways: (1) "Midazolam attaches to GABA receptors," as well as (2) "inhibiting GABA." J.A.293, 312-13. Not surprisingly, Dr. Evans' testimony on this point did not draw a single question on cross-examination. At worst, Dr. Evans' testimony can be criticized for being "unclear," as stated by Petitioners' expert in his after-the-fact declaration. J.A.281. In any event, none of

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[19] Petitioners also criticize Dr. Evans' reliance on drugs.com but, notably, do not question the accuracy of any of the information contained therein. Cf. J.A.325-26. Drugs.com states that it "provides accurate and independent information," but contains a *consumer* disclaimer that is present in nearly every medical publication, including journals upon which Petitioners' experts rely. See, e.g., Anesthesiology, Terms and Conditions of Use, http://anesthesiology.pubs.asahq.org/ss/terms.aspx ("None of the information on this Site shall be used to diagnose or treat any health problem or disease.").

the purported mistakes made by Dr. Evans – and they are not mistakes – were relied upon by in the district court's or the court of appeals' review of those findings. J.A.75, 134-37.

Petitioners also ignore that the district court did not reach its factual findings in a vacuum: the court also had before it the testimony of Petitioners' expert, Dr. Lubarsky, which was so riddled with speculation, unsubstantiated claims, and internal contradiction that the district court did not clearly err in crediting Dr. Evans' testimony over Dr. Lubarsky's. See *Anderson* v. *Bessemer City*, 470 U.S. 564, 575 (1985) ("when a trial judge's finding is based on his decision to credit the testimony of one of two or more witnesses, * * * that finding, if not internally inconsistent, can virtually never be clear error"). As noted above, Dr. Lubarsky's testimony on the limited lethal toxicity is wholly unsubstantiated and contradicted by the record. Also left unsupported was his claim of reports of paradoxical effects occurring after sedation. P.23, *supra*. His unsupported claim that pentobarbital is approved as a sole anesthetic is contradicted by the drug's label. *Ibid.* His testimony on midazolam's anesthetic capabilities contradicted the testimony of Petitioners' other expert and even his own testimony. Pp.24-25. Dr. Lubarsky also testified, incredibly, that *sodium thiopental* was "insufficient to render a patient unconscious through the entirety of the execution" and its use was "constructed to produce egregious harm and suffering" – a claim that not even the petitioners faced with impending death in

Baze were willing to make. J.A.226-27. And his reports and declarations consistently misconstrue medical literature. Pp.22-23.

Scholars, as well as members of this Court, have criticized Lubarsky's claims regarding lethal injection drugs. Pp.18-19, *supra*. Courts have consistently rejected Dr. Lubarsky's testimony regarding the anesthetic effects of drugs used in lethal injections, including midazolam. See, e.g., *Chavez*, 742 F.3d at 1269-73; *Howell*, 133 So.3d at 518-22; *West* v. *Schofield*, 380 SW.3d 105, 114-16 (Tenn. 2012); *Brown* v. *Crawford*, 408 F.3d 1027 (8th Cir. 2005). The district court did not clearly err in doing the same.

C. Petitioners' Speculative Criticisms Of Midazolam Do Not Establish That Its Use Puts Them At Substantial Risk Of Serious Harm.

The criticisms Petitioners level at midazolam are largely similar to those leveled at sodium thiopental and pentobarbital, and which were ultimately proven to be nothing but speculations: that midazolam (1) is not an analgesic, (2) can cause paradoxical reactions, and (3) has a ceiling effect.

1. Midazolam's analgesia has no relevance to whether it can render an inmate unconscious and unaware of pain.

Midazolam is not considered to be an analgesic. Neither are sodium thiopental and pentobarbital. See, e.g., DailyMed, *Label: Thiopental Sodium – thiopental sodium injection, powder, for solution* (Feb. 2011), 1.usa.gov/1bPLDbM; *United States* v. *Turner*, 38 C.M.R. 757, 759 (N.B.R. 1968), *reversed on other grounds*, 39 C.M.R. 55 (C.M.A. 1968). That lack of analgesia has never had any impact on this and other courts' determinations that sodium thiopental and pentobarbital were constitutionally-sound choices as the first drug in three-drug protocols. In *Baze*, for example, Petitioners' expert witness testified that sodium thiopental was not an analgesic and suggested that it in fact had anti-analgesic effects. Joint Appendix vol. II, *Baze* v. *Rees*, No. 07-5439, 2007 WL 4790797, *434-35. None of the opinions rendered in the case mentioned analgesia as a factor relevant to the Eighth Amendment analysis.

Midazolam's lack of analgesic qualities has no bearing on its effectiveness in rendering Petitioners unconscious and insensate. As the district court correctly found, pain relief is only necessary for a patient who is aware of pain in the first instance. When the patient is unconscious and unaware of pain, there is no need for analgesia. J.A.77, 314-15; see also Pet. Br. 3 (acknowledging barbiturates "eliminate the risk that a prisoner will feel pain," though they too are not

analgesics); *Howell*, *supra* n.2, IX Supp.R. at 217-19 (when unconscious under midazolam, a person is "oblivious to all external stimuli" and unable to "consciously process" pain). And unlike surgeries, where analgesia is helpful in reducing the pain the patient will feel upon awakening, in a lethal injection, there is no similar need for analgesia.

2. The risk of paradoxical effects from midazolam does not pose a substantial risk of pain.

In a very small percentage of cases, paradoxical reactions occur with benzodiazepines, J.A.78, just as they do with other drugs – even barbiturates like pentobarbital, see, e.g., J. Hayden, Jr. et al., *Paradoxical Reaction to Intravenous Pentobarbital, Meperidine, and Scopolamine*, 21 Anesthesia Progress 82, 82-83 (1974). In these instances, rather than rendering the recipients unconscious, midazolam causes them to become agitated and even combative. J.A.172-73. This *slight* chance of a paradoxical reaction does not create a *substantial* risk that Petitioners will not be unconscious when the second and third drugs are administered. J.A.78-79.

If a paradoxical reaction is occurring, Oklahoma's use of trained medical personnel – here, a physician and a paramedic, both highly-qualified and trained – to monitor the administration of midazolam ensures that the inmate will never be declared unconscious,

and the second and third drugs will never be administered. Pp.16-17, *supra*; Tr.374-75.

Petitioners could point to only two case reports of paradoxical reactions manifesting after midazolam sedations – reactions to low doses which did not result in any pain awareness – out of the tens of millions of administrations of midazolam that have occurred over the past several decades. See pp.25-26, *supra*. Petitioners' expert claimed to have overseen a million administrations of midazolam, yet never claimed to have witnessed such a late-manifesting reaction. A two-in-many-millions chance does not a "substantial risk" make.

3. Petitioners failed to present any evidence that midazolam has a ceiling effect that would prevent a 500mg dose from rendering them unconscious and insensate to pain.

Petitioners claim midazolam is subject to a "ceiling effect" and, as a result, "[t]he medical consensus is that midazolam cannot generate deep, comalike unconsciousness." Pet. Br. 26. Yet, even if midazolam does produce a ceiling effect, the legally relevant question is whether that effect impacts midazolam's ability to render the recipient unconscious and insensate. And, the medical consensus is clear on this issue, as evidenced by Midazolam's FDA Label, which warns that a larger-than-therapeutic dose can result in coma and death, p.5, *supra*, an effect much greater

than that needed to comply with the Eighth Amendment bar on cruel and unusual punishment.

The sources that Petitioners' expert relied upon – in a declaration submitted to the court of appeals and never presented to the district court – merely hypothesize that there *might* be a ceiling effect with midazolam, though no testing ever established that "ceiling." *Supra*, n.14. One study actually described the dosage at which midazolam could serve as a sole anesthetic. *Ibid.* When pressed, Petitioners' expert admitted he could not render an opinion as to the dosage at which this alleged ceiling was reached. J.A.225.

It is unsurprising that the district court concluded that Petitioners' evidence on this point failed to establish a probability of success on the merits. Petitioners' evidence was speculative at best. J.A.94-96, 99 (citing *Brewer* v. *Landrigan*, 131 S. Ct. 445 (2010)).

By contrast, Oklahoma's expert offered persuasive testimony that was consistent with both the FDA's findings and testimony of several other experts in litigation in Florida. For example, consistent with Midazolam's FDA Label, Dr. Evans testified that a large dose of midazolam would induce a coma. Tr.661. Dr. Mark Dershwitz, an expert anesthesiologist who has published research on midazolam, testified in Florida that "a 500 mg dose of midazolam places the recipient in a coma," which the court accepted while rejecting Dr. Lubarsky's testimony. *Howell*, 133 So.3d

at 521.[20] In separate Florida litigation, Dr. Mark Heath, *an expert testifying for the condemned*, "agreed that the dosage of midazolam hydrochloride called for in the protocol, if properly administered together with adherence to the procedures for determining consciousness, will result in an individual who is deeply unconscious and who would feel no pain when the remaining drugs are administered." *Muhammad*, 132 So.3d at 195; see also *id.* at 193-94 (noting testimony by Dr. Heath that midazolam "will have full efficacy as an anesthetic" such that even a 10 or 15mg dose "will reliably produce a much deeper level of unconsciousness" and a 500mg dose "is a much larger dose than that needed to produce unconsciousness and * * * would, with certainty, produce death"). The district court properly credited Oklahoma's evidence over Petitioners' evidence.

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[20] When contrasting Dr. Lubarsky's conjectural testimony with that of Dr. Dershwitz, the Florida Supreme Court noted that, "when asked questions as to the effects of 500 mg on a person, Dr. Lubarsky had to speculate as to the results." *Howell*, 133 So.3d at 522. By contrast, Dr. Dershwitz used midazolam as "the first and primary drug to induce anesthesia" in neurosurgeries and testified based on his direct experience that "where a 50 mg dose prevented his patients from perceiving the noxious stimuli associated with neurosurgery, [ ] it was clear a 500 mg dose would prevent the recipient from being 'able to perceive any noxious stimuli whatsoever.'" *Ibid.*

4. Oklahoma's robust procedural safeguards obviate the risk of insufficient anesthesia.

Petitioners have no complaints with the procedural safeguards Oklahoma has employed to ensure proper administration of the drug protocol and to determine and monitor unconsciousness.

Rightly so. Oklahoma's revamped execution procedures address each and every procedural concern raised in *Baze*. For example, the dissent in *Baze* suggested that (1) medical personnel monitor the inmate's face and IV point on closed circuit television; (2) medical personnel physically confirm the inmate's unconsciousness, through medically appropriate means, like brushing the inmate's eyelids, shaking the inmate, saying the inmate's name, and applying noxious stimuli; (3) a mandatory amount of time be allowed to elapse after administration of the first drug, and prior to the administration of the second and third drugs; and (4) the use of an EKG to monitor unconsciousness. *Baze*, 553 U.S. at 120 (Ginsburg, J., dissenting). The plurality held that Kentucky's execution protocol did not create a substantial risk of serious harm despite not having any of these safeguards. See *id.* at 54-56. Oklahoma's execution protocol has *all* of them. J.A.63-66; Execution Protocol 43 (Doc. 117-2).

Oklahoma's procedural safeguards are relevant. In *Baze*, the claim was that deficiencies in Kentucky's procedural safeguards could be obviated by a change

in drug protocol. The converse is also true. An alleged deficiency in a drug protocol can be obviated by robust procedural safeguards. Both the drug and procedural protocols lower the risk of pain. The district court accordingly found highly relevant three parts of the revised lethal injection protocol: (1) "both primary and backup IV access sites be established"; (2) "viability of the IV sites" be confirmed; and (3) "the offender's level of consciousness [] be monitored throughout the procedure." J.A.97. Indeed, these three safeguards, in addition to all the other safeguards utilized by Oklahoma – for example, the use of highly-trained medical personnel – fully mitigate any alleged risk of pain that might arise from use of midazolam.

* * *

Much like the attacks leveled at sodium thiopental and pentobarbital, which turned out to be unwarranted after both drugs established a solid record of reliably rendering inmates deeply unconscious, the attacks leveled at midazolam here are unwarranted.

Oklahoma has already conducted an execution using the drug protocol at issue here. The execution was completed without incident, and, by all accounts, the midazolam worked exactly as intended. Pp.32-33, *supra*. There was no paradoxical reaction, no "ceiling effect" that prevented the midazolam from rendering the inmate deeply unconscious, and no need for analgesia because the inmate was deeply unconscious. Likewise, the eleven executions carried out by

Florida using an identical protocol establish that a 500mg intravenous dose of midazolam reliably renders the inmates deeply unconscious and unaware of pain. Neither the district court nor the court of appeals abused their discretion in upholding Oklahoma's execution protocol.

III. PETITIONERS FAILED TO SATISFY EVEN THE MOST RELAXED OF PRELIMINARY INJUNCTION STANDARDS.

Petitioners' second question presented asks whether the *Baze* standard applies to challenges of drug protocols not substantially similar to the one at issue in *Baze*. Every court of appeals that has considered this issue has concluded that it does so apply, pp.61-62, *infra*, and correctly so.

The standard set forth by the *Baze* plurality mandates that "[a] stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain * * * [that] is substantial when compared to the known and available alternatives." *Baze*, 553 U.S. at 61. Critically, the next line in the opinion explains that "[a] State with a lethal injection protocol substantially similar to the protocol we uphold today would not create a risk that meets this standard." *Id.* Because the Court blessed all "substantially similar" protocols, the standard articulated by the Court was necessarily intended for

application to *dis*similar protocols. Thus, the answer to the second question presented is a straightforward "yes," and there is no good reason to set aside the circuit courts' consensus on this point.

Unsurprisingly, then, Petitioners have transformed that question into something altogether different and new: whether the Tenth Circuit applied the wrong preliminary injunction standard. Even on this question, on which this Court has not granted certiorari, Petitioners are incorrect.

1. The court of appeals explicitly applied the "significant probability of success on the merits" standard articulated by this Court in *Hill* v. *McDonough*, 547 U.S. 573, 584 (2006). J.A.121 n.5 (rejecting the standard proposed by Petitioners in favor of the *Hill* standard); see also J.A.113, 120, 138. The court of appeals should be taken at its word. This Court has long been deferential to lower courts with regard to whether they applied proper standards of review. See, e.g., *Wainwright* v. *Witt*, 469 U.S. 412, 431 (1985) (holding that a trial court is presumed to have applied the correct standard, even in cases where the record is silent as to what standard was applied).

2. Petitioners point to the Tenth Circuit's description of the *Baze* standard as their evidence that it *sub silentio* substituted that standard in place of the preliminary injunction standard. Pet. Br. 39. But in order to properly apply the "significant probability of success on the merits," a court must first *define* success on the merits. Only by doing so can the court

accurately measure whether the movant has made the requisite "clear showing" that he has a significant probability of success. *Hill*, 547 U.S. at 584 (citing *Mazurek* v. *Armstrong*, 520 U.S. 968, 972 (1997)). Placing this burden on the movant is critical, because "a stay of execution is an equitable remedy" that is "not available as a matter of right," and "equity must be sensitive to the State's strong interest in enforcing its criminal judgments without undue interference from the federal courts." *Ibid.*

3. In any event, the district court heard three days of testimony, made credibility determinations, and weighed the evidence when determining that Petitioners had not made that clear showing of a significant probability of success. J.A.41. The district court went one step further and held that Petitioners had failed to meet even the more relaxed standard that the Tenth Circuit applies when a movant has satisfied the other three prongs of the preliminary injunction test: whether Petitioners had "raised questions going to the merits so serious, substantial, difficult and doubtful, as to make them a fair ground for litigation." J.A.41 (citing *Kikumura* v. *Hurley*, 242 F.3d 950, 955 (10th Cir. 2001)). In other words, no matter the standard, Petitioners failed to meet it.

4. While ultimately beside the point here, the *Baze* standard *should* in fact apply to all requests for a stay "on grounds such as those" asserted there. The *Baze* plurality articulated its standard of when "[a] stay of execution may not be granted" in answer to Justice Stevens' criticism that the "opinion leaves the

disposition of *other* cases uncertain," *Baze*, 553 U.S. at 61 (emphasis added), thus speaking to future cases like this one. *Baze* applies any time a stay of execution is requested.

Petitioners argue that their case is distinct from *Baze* in that the *Baze* petitioners conceded that the "State's method, if administered according to plan, would be constitutional." J.A.27. Hardly so. There, as here, the petitioners claimed that the State's chosen drug protocol was *inherently* unconstitutional because it was *impossible* for Kentucky to administer it in a way that did not place them at risk of pain. Compare Pet. Br. 27 with Reply Br. for Pet'rs, *Baze* v. *Rees*, 2007 WL 4618321, *1 ("Kentucky has built into its execution procedures an inherent danger of inflicting excruciating pain upon condemned prisoners."). Because Petitioners' claims challenge a method of execution – "grounds like those" asserted in *Baze* – a "stay of execution may not be granted" unless they satisfy the *Baze* standard. *Id.* at 61.

IV. PETITIONERS FAILED TO SHOW THAT ANY RISK WOULD BE SUBSTANTIAL AS COMPARED TO AVAILABLE ALTERNATIVES.

Baze holds that, after making a threshold showing of a "demonstrated risk of severe pain," the prisoner "must show that the risk is substantial *when compared to the known and available alternatives*" to succeed on an Eighth Amendment challenge to a

method of execution. *Baze*, 553 U.S. at 61. The Tenth Circuit resolved the case at the first step of the inquiry, finding it "not even 'necessary in this case to reach the second step of the *Baze* test,'" but nonetheless correctly noted that Petitioners' failure to identify a single "known and available alternative" provided a second, independent basis for rejecting Petitioners' claim. J.A.130 & n.9 (citation omitted). Petitioners challenge this alternative holding, arguing that *Baze*'s second step applies only to challenges seeking "to force the State to adopt a substantially improved method in lieu of its concededly constitutional method." Pet. Br. 50.

1. Contrary to Petitioners' characterizations, *Baze* did not involve a challenge to a "concededly constitutional method." P.60, *supra*. Not surprisingly, every Circuit that has considered the issue has endorsed the Tenth Circuit's straightforward reading of *Baze* as the standard for *all* cases challenging methods of execution, not just those seeking to substitute a concededly-constitutional method. See, e.g., *Zink* v. *Lombardi*, ___ F.3d ___, 2015 WL 968176, *8-10 (8th Cir. Mar. 6, 2015) (en banc); *Whitaker* v. *Livingston*, 732 F.3d 465, 468 (5th Cir. 2013); *Mann* v. *Palmer*, 713 F.3d 1306, 1315 (11th Cir. 2013); *Jackson* v. *Danberg*, 656 F.3d 157, 163-65 (3d Cir. 2011); *Pavatt* v. *Jones*, 627 F.3d 1336, 1339 (10th Cir. 2010); *Cooey* v. *Strickland*, 589 F.3d 210, 220 (6th Cir. 2009); see also *Chavez*, 742 F.3d at 1273-74 (Carnes, C.J., concurring) (stating, in case challenging use of midazolam, "[t]he Court could not have been clearer" that

"the inmate must prove * * * that there is a 'known and available alternative'" as an "element of a claim" under the Eighth Amendment).

Thus, the Tenth Circuit was correct to join its sister courts in holding that the *Baze* standard was "intended to apply to all challenges to 'a State's chosen procedure for carrying out a sentence of death.'" J.A.131 (quoting *Baze*, 553 U.S. at 48); see also *Baze*, 553 U.S. at 70 (Alito, J., concurring) ("The issue presented in this case" is "the constitutionality of a *method* of execution."); *Zink*, 2015 WL 968176 at *8-10; J.A.89-91. Indeed, the *Baze* plurality explicitly articulated its intention to apply this standard to a broad class of cases, *Baze*, 553 U.S. at 61, in direct response to Justice Stevens' concern that the holding would provide insufficient guidance on other cases concerning "lethal injection as a method of execution," *id.* at 71. See also *id.* at 102-03, 106 (Thomas, J., concurring) (recognizing that the plurality adopted a comparative standard for all Eighth Amendment claims); *id.* at 116 (Ginsburg, J., dissenting) (stating that, in challenges to methods of execution, the "availability of alternatives must be considered"); *id.* at 107-08 (Breyer, J., concurring) (same).

2. *Baze*'s requirement that challengers to an execution method identify a less painful and available alternative flows directly from this Court's longstanding Eighth Amendment jurisprudence. "We begin with the principle * * * that capital punishment is

constitutional." *Baze*, 553 U.S. at 47 (citing *Gregg*, 428 U.S. at 177). "It necessarily follows that there must be a means of carrying it out," even if "[s]ome risk of pain is inherent in any method of execution." *Baze*, 553 U.S. at 47.

An Eighth Amendment challenge to a method of execution that fails to identify an available alternative necessarily challenges as cruel and unusual the pain inflicted "as an inescapable consequence of death" – a challenge to the death penalty itself. *Baze*, 553 U.S. at 50. Accordingly, the *Baze* standard correctly requires petitioners challenging a method of execution – but not capital punishment itself – to demonstrate an available alternative lest a State's constitutional prerogative to provide for capital punishment be abrogated by having its chosen form of execution declared unconstitutional without any alternative to effectuate its laws. See *id.* at 61 ("The power of a State to pass laws means little if the State cannot enforce them." (quoting *McCleskey* v. *Zant*, 499 U.S. 467, 491 (1991))); *Baze*, 553 U.S. at 64 (Alito, J., concurring) ("Since we assume for present purposes that lethal injection is constitutional, the use of that method by the Federal Government and the States must not be blocked by procedural requirements that cannot practicably be satisfied.").

Petitioners complain that the *Baze* standard could make the constitutionality of an execution method hinge on the decisions of third parties, Pet. Br. 52, such as the decisions of death penalty opponents to

deprive States of the drug that make execution painless. But, as demonstrated above, that is the logical and necessary result of the Constitution's endorsement of capital punishment and a consequence recognized by the *Baze* plurality. *Baze*, 553 U.S. at 59-60; see also *id.* at 64-66 (Alito, J., concurring) (recognizing that challenge to method of execution based on lack of physician supervision is foreclosed by professional society's ethics rules prohibiting that supervision); *id.* at 112 (Breyer, J., concurring) (same).

3. None of this Court's decisions, before or after *Baze*, are to the contrary. Unlike *Baze*, *Hill* did not purport to rule on the elements necessary to prove a method of execution is cruel and unusual under the Eighth Amendment. Rather, the question in *Hill* was whether such a challenge "must be brought by an action for a writ of habeas corpus * * * or whether it may proceed as an action for relief under" Section 1983. *Hill*, 547 U.S. at 576. In examining "the legal distinction between habeas corpus" and claims under Section 1983, the Court held that Section 1983 itself did not impose "heightened pleading requirements" above those provided for in Rule 8. *Id.* at 581-82. Accordingly, a plaintiff need not plead an acceptable alternative in a Section 1983 suit, unless he is required to plead it as an element of proving an Eighth

Amendment challenge in other contexts, such as habeas corpus. *Ibid.*[21]

Jones v. *Bock* underscores this point. 549 U.S. 199 (2007). There, the question was whether the Prisoner Litigation Reform Act, which requires exhaustion of administrative remedies, mandated dismissal of a Section 1983 complaint that failed to plead exhaustion. *Id.* at 204. Starting with the noncontroversial proposition that Section 1983 itself did not require exhaustion, the Court next looked to the Act, to see whether Congress treated exhaustion as an element of the claim, or as an affirmative defense. *Id.* at 212. Concluding that the Act "does not itself require plaintiffs to plead exhaustion," the Court held that, "the usual practice" of treating exhaustion as an affirmative defense should be followed, and therefore it need not be pleaded. *Id.* at 212, 217.

After *Baze*, the Eighth Amendment "itself requires plaintiffs to plead" an available alternative form of execution when challenging a method of execution. Not surprisingly, then, *Baze* never mentioned *Hill* because those decisions addressed two entirely

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[21] Indeed, "Hill concede[d] that 'other methods of lethal injection * * * would be constitutional' " such that "Hill's action if successful would not necessarily prevent the State from executing him." *Hill*, 547 U.S. at 580. Whether on consideration of the merits the State would challenge this allegation and whether Hill would be able to prove availability had remained to be seen. *Id.* at 585. Here, Petitioners have not made any showing that any available and authorized alternative form of execution could be implemented. J.A.428.

separate questions, with the former concerning the elements of an Eighth Amendment claim and the latter focusing on the pleading standards imposed by Section 1983.

Thus, as the en banc Eighth Circuit correctly observed, "*Hill* did not address the elements of a successful claim under the Eighth Amendment," but rather "concerned only the *cognizability* of a complaint" under Section 1983 rather than habeas. *Zink*, 2015 WL 968176 at *10. "Whether Hill's complaint stated a claim for relief under Rule 8 and the Eighth Amendment is a question that 'goes to the merits' of the underlying action" and a question that was not addressed until *Baze* set forth "the elements of a claim challenging a lethal-injection protocol," including the necessity of demonstrating an available constitutional alternative. *Ibid.* (quoting *Bond* v. *United States*, 131 S. Ct. 2355, 2362 (2011)). Indeed, in *Nelson*, on which *Hill* primarily relied, this Court noted that "[i]f on remand and after an evidentiary hearing the District Court concludes that use of the [challenged] procedure * * * is necessary for administering the lethal injection, the District Court will need to address the broader question, *left open here*, of how to treat method-of-execution claims generally." *Nelson* v. *Campbell*, 541 U.S. 637, 646 (2004) (emphasis added).

CONCLUSION

The petition should either be dismissed as improvidently granted, or the judgment of the Tenth Circuit should be affirmed.

Respectfully submitted,

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APPENDIX

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The Eighth Amendment to the United States Constitution provides, in relevant part, that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII.

Title 42, section 1983, of the United States Code states that "[e]very person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress." 42 U.S.C. § 1983.